



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hungerford et al *

Serial No.: 10/039,718 * Art Unit: 1651

Date Filed: January 3, 2002 * Examiner: Mr. David M. Naff

For: CELL-CULTURE AND POLYMER *
CONSTRUCTS *

DECLARATION UNDER 37 C.F.R. § 1.132

To the Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Carmelita G. Frondoza, declare:

1. That I reside at 9707 Slalom Run Drive, Woodstock, Maryland 21163.
2. That I hold a Ph.D. degree in Immunology from Johns Hopkins University.
3. That I belong to several professional organizations concerned with biotechnology and tissue engineering including the Orthopaedic Research Society, the Tissue Engineering Society International, and the Society for Biomaterials.
4. That I have authored or co-authored several publications in the fields of tissue engineering and cell culture.
5. That my employment has involved a career in tissue engineering that includes

selection of cell culture bioreactors, including stirred bioreactors such as spinner culture systems, bioreactors for culturing cells in space (microgravity), and bioreactors that produce microgravity conditions for use in normal gravity conditions.

6. That I am presently employed by the Department of Orthopaedic Surgery at Johns Hopkins University, 5601 Loch Raven Boulevard, Baltimore, MD 21239.

7. That because of my education, training and experience, I qualify as an expert in the field of cell culture and tissue engineering.

8. That I am a co-inventor and have read and understand the above-titled application.

9. That I have read and understand the Examiner's Official Action of May 3, 2005.

10. The Examiner states in his Official Action that,

when culturing chondrocytes for implanting as disclosed by *Glorioso et al*, it would have been obvious to culture the chondrocytes on a microcarrier in a spinner flask as suggested by *Frondoza et al* disclosing this method of culturing as supporting chondrocyte growth and enhancing phenotype, and as further suggested by *Schinistine et al* disclosing culturing cells on microcarriers to prevent the formation of necrotic regions and as also suggested by *Cherksey* disclosing that culturing cells on glass beads before transplanting into the mammalian brain results in prolonged survival and viability *in vivo*.

11. Declarant states that, although *Frondoza et al* and *Glorioso et al* both employ chondrocytes in their methods, the fact that *Glorioso et al* employs transfected chondrocytes as opposed to natural chondrocytes would render the *Glorioso et al* chondrocytes non-analogous and lacking in equivalency. This is so because introducing a DNA sequence (transfection) into a chondrocyte would have the effect of rendering the phenotype characteristic of the cultured

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chondrocyte unpredictable and would render the growth pattern (phenotype) of the chondrocyte during culture to be unpredictable.

12. That I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

6/21/05
Date

Carmelita G. Frondoza
CARMELITA G. FRONDOZA